

Remarks

Reconsideration of the above-identified application in view of the present amendment is respectfully requested. Claims 1-7, 9, 10, 12, 13, 15-33, and 35-54 are pending in the present application. Claims 1 and 53 have been amended.

Title Objection

The Title was objected to for being non-descriptive. The Title has been amended to overcome this objection.

Double Patenting

The Office Action of October 26, 2006 noted that the double patenting rejection of claims 1, 2, 7, 8, 17, 21, 30, 33, 34, and 36 should have been based on U.S. Patent No. 6,527,774 instead of U.S. Patent No. 6,517,774. The error was typographical in nature. A new Terminal Disclaimer is accompanied herewith to remedy this mistake.

The Office Action also rejected claims 1, 2, 6, 7, 17, 21, 24, 30, 33, 36, 53, and 54 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent Nos: 6,488,683, 6,468,309, 6,551,322, 6,544,265, 6,551,319, 6,551,320, 6,689,168, 6,527,774, and 6,953,462. A Terminal Disclaimer is accompanied herewith to overcome this rejection.

Rejections under 35 U.S.C. §101

Claims 1, 2, 6, 7, 17, 53, and 54 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claims 1 and 53 have been amended to recite that the distal end of the helical spikes has a tip portion *for penetrating* into bone. It is believed that this amendment overcomes the rejection to claims 1 and 53 in that the claim no longer positively

recites a portion of the human body. Therefore, it is believed that the rejection to dependent claims 2, 6, 7, 17, and 54 has likewise been overcome.

Rejections under 35 U.S.C. §102

In the Office Action of October 26, 2006, claims 1, 2, 6, 7, 17, 21, 24, 30, 33, 36, 53, and 54 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,582,616 to Bolduc (hereinafter 'Bolduc). It is respectfully submitted that, as amended, claim 1 is not anticipated by Bolduc, and is therefore allowable.

As amended, claim 1 recites an apparatus for attaching a first bone to an adjacent second bone, the second bone being separated from the first bone by a space between the adjacent bones. The apparatus comprises an anchor having a platform for drivingly rotating the anchor and at least two helical spikes for embedding into at least one of the first and second bones upon rotation of the platform. The platform has a first surface that is solid and that extends generally transverse to a longitudinal axis of the anchor. The platform further has a second surface disposed opposite the first surface and a cylindrical outer surface extending between the first surface and second surface. The at least two helical spikes project tangentially from the first surface of said platform and extend around the longitudinal axis.

Bolduc appears to teach that proximal end 118 of fastener 110 has a connector bar 122 sectioning the diameter of the fastener that connects one helical coil to another and functions to receive and transmit longitudinal forces (Col. 7, lines 48-52 and Fig. 2C). Connector bar 122 has only one surface, and thus is not a platform having a first surface, a second surface, and a cylindrical outer surface extending therebetween, as recited in amended claim 1.

Furthermore, Bolduc appears to teach a helical fastener 10 that is attached to tissue by an applicator 12 which rotates fastener 10 into the tissue (Col. 6, lines 12-16 and Fig. 1). As the fastener 10 is pressed against tissue 25, all the coils substantially collapse except the most distal coil 27, leaving gap 23 to determine the path the fastener 10 takes as it is rotated into tissue 25 and the extent of penetration 29 into the tissue 25 (Col. 6, lines 50-55 and Figs. 1B-1E). The fastener 10 is used in such medical procedures as ligating tissue, hernia mesh repair, bladder neck suspension, or otherwise positioning surgical or implantable devices in the patient's body (Col. 2, lines 45-52). The fastener 10 is simply not structurally sound enough, nor designed for, implantation into bone, as the present invention is. The fact that fastener 10 is almost fully collapsable, and inserted into tissue 25 simply by manipulating lever 54 to drive nut driver 62 along lead screw 64 (Col. 9, lines 46-60 and Fig. 5) suggests that both the fastener 10 and applicator 12 are incapable of use in bone. Since Bolduc does not teach or suggest the subject matter of amended claim 1, it is respectfully submitted that as amended, claim 1 is not anticipated by Bolduc, and is therefore allowable.

Claims 2, 6, 7, and 17 depend from claim 1 and are allowable for at least the same reasons claim 1 is allowable, and for the specific limitations recited in each claim.

Claim 21 recites an apparatus for attaching a fifth lumbar (L5) vertebrae to a sacrum, the apparatus comprising an anchor for extending between the L5 vertebrae and the sacrum and for attaching the L5 vertebrae to the sacrum. The anchor has a platform for drivingly rotating the anchor. The platform includes a first surface that is solid and that extends generally transverse to a longitudinal axis of the anchor. The platform has second surface disposed opposite the first surface and a cylindrical outer surface extending between the first surface and the second surface. The anchor further has at least two helical spikes for

embedding into both of the L5 vertebrae and the sacrum upon rotation of the platform, the at least two helical spikes projecting tangentially from the first surface of the platform and extending around the longitudinal axis. The at least two helical spikes have a tip portion at a distal end for penetrating into at least one of the L5 vertebrae and the sacrum as the platform is rotated. The anchor has a first condition in which the at least two helical spikes are embeddable into one of the L5 vertebrae and the sacrum. The anchor further has a second condition in which the at least two helical spikes are embeddable into both of the L5 vertebrae and the sacrum to attach the L5 vertebrae and the sacrum to one another while maintaining an intervertebral space between the L5 vertebrae and the sacrum. The anchor is movable from the first condition to the second condition by rotation of the platform. A portion of each of the at least two helical spikes of the anchor, when the anchor is embedded into the L5 vertebrae and the sacrum, extends across the intervertebral space between the L5 vertebrae and the sacrum.

Bolduc appears to teach that proximal end 118 of fastener 110 has a connector bar 122 sectioning the diameter of the fastener that connects one helical coil to another and functions to receive and transmit longitudinal forces (Col. 7, lines 48-52 and Fig. 2C). Connector bar 122 has only one surface, and thus is not a platform having a first surface, a second surface, and a cylindrical outer surface extending therebetween, as recited in amended claim 21.

Furthermore, Bolduc appears to teach a helical fastener 10 that is attached to tissue by an applicator 12 which rotates fastener 10 into the tissue (Col. 6, lines 12-16 and Fig. 1). As the fastener 10 is pressed against tissue 25, all the coils substantially collapse except the most distal coil 27, leaving gap 23 to determine the path the fastener 10 takes as it is rotated into

tissue 25 and the extent of penetration 29 into the tissue 25 (Col. 6, lines 50-55 and Figs. 1B-1E). The fastener 10 is used in such medical procedures as ligating tissue, hernia mesh repair, bladder neck suspension, or otherwise positioning surgical or implantable devices in the patient's body (Col. 2, lines 45-52). The fastener 10 is simply not structurally sound enough, nor designed for, implantation into the L5 vertebrae and sacrum (i.e. bone), as the present invention is. The fact that fastener 10 is almost fully collapsable, and inserted into tissue 25 simply by manipulating lever 54 to drive nut driver 62 along lead screw 64 (Col. 9, lines 46-60 and Fig. 5) suggests that both the fastener 10 and applicator 12 are incapable of use in bone. Since Bolduc does not teach or suggest the subject matter of amended claim 21, it is respectfully submitted that as amended, claim 21 is not anticipated by Bolduc, and is therefore allowable.

Claims 24, 30, 33, and 36 depend from claim 21 and are allowable for at least the same reasons claim 21 is allowable, and for the specific limitations recited in each claim.

As amended, claim 53 recites an apparatus for attaching a first bone to an adjacent second bone. The second bone is separated from the first bone by a space between the adjacent bones. The apparatus comprises an anchor having a platform for drivingly rotating the anchor and at least two helical spikes for embedding into at least one of the first and second bones. Upon rotation of the platform, the platform has a first surface that extends generally transverse to a longitudinal axis of the anchor. The platform further has a second surface disposed opposite the first surface and a cylindrical outer surface extending between the first surface and the second surface. At least two helical spikes project from the first surface of the platform and extend around the longitudinal axis. The at least two helical spikes have a tip portion at a distal end for penetrating into bone as the platform is rotated.

The anchor has a first condition in which a first portion of each of the at least two helical spikes is extendable into one of the first and second bones. The anchor further having a second condition in which the first portions are extendable into the other of the first and second bones and a second portion of each of said at least two helical spikes is extendable into the one bone to attach the first and second bones to one another while maintaining the space between the bones. Each of the at least two helical spikes further includes a third portion extending between the first and second portions and that, when the anchor is embedded into the first and second bones, extends across the space between the bones, wherein one of the first and second bones is the sacrum and the other of said first and second bones is the fifth lumbar (L5) vertebrae.

Bolduc appears to teach that proximal end 118 of fastener 110 has a connector bar 122 sectioning the diameter of the fastener that connects one helical coil to another and functions to receive and transmit longitudinal forces (Col. 7, lines 48-52 and Fig. 2C). Connector bar 122 has only one surface, and thus is not a platform having a first surface, a second surface, and a cylindrical outer surface extending therebetween, as recited in amended claim 53.

Furthermore, Bolduc appears to teach a helical fastener 10 that is attached to tissue by an applicator 12 which rotates fastener 10 into the tissue (Col. 6, lines 12-16 and Fig. 1). As the fastener 10 is pressed against tissue 25, all the coils substantially collapse except the most distal coil 27, leaving gap 23 to determine the path the fastener 10 takes as it is rotated into tissue 25 and the extent of penetration 29 into the tissue 25 (Col. 6, lines 50-55 and Figs. 1B-1E). The fastener 10 is used in such medical procedures as ligating tissue, hernia mesh repair, bladder neck suspension, or otherwise positioning surgical or implantable

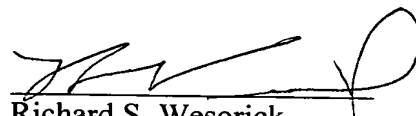
devices in the patient's body (Col. 2, lines 45-52). The fastener 10 is simply not structurally sound enough, nor designed for, implantation into the L5 vertebrae and sacrum (i.e. bone), as the present invention is. The fact that fastener 10 is almost fully collapsable, and inserted into tissue 25 simply by manipulating lever 54 to drive nut driver 62 along lead screw 64 (Col. 9, lines 46-60 and Fig. 5) suggests that both the fastener 10 and applicator 12 are incapable of use in bone. Since Bolduc does not teach or suggest the subject matter of amended claim 53, it is respectfully submitted that as amended, claim 53 is not anticipated by Bolduc, and is therefore allowable.

Claim 54 depends from claim 53 and is allowable for at least the same reasons claim 53 is allowable, and for the specific limitations recited therein.

In view of the foregoing, it is respectfully submitted that the above-identified application is in condition for allowance, and allowance of the application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this amendment to our Deposit Account No. 20-0090.

Respectfully submitted,



Richard S. Wesorick
Reg. No. 40,871

TAROLLI, SUNDHEIM, COVELL &
TUMMINO L.L.P.
1300 East Ninth Street, Suite 1700
Cleveland, OH 44114
Phone: (216) 621-2234
Fax: (216) 621-4072
Customer No.: 26,294